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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/717,738	11/20/2003	Hiroyuki Odaka	087147-0604	8700
22428 7590 12/15/2008 FOLEY AND LARDNER LLP SUITE 500 3000 K STREET NW WASHINGTON, DC 20007				
EXAMINER				
WEDDINGTON, KEVIN E				
ART UNIT		PAPER NUMBER		
1614				
MAIL DATE		DELIVERY MODE		
12/15/2008		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/717,738

Applicant(s)

ODAKA ET AL.

Examiner

Kevin E. Weddington

Art Unit

1614

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 November 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 31-36 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 31-36 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/CDC)
- 4) ☐ Interview Summary (PTO-413)
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____
- Paper No(s)/Mail Date _____

The finality of the Office action dated July 11, 2008 has been withdrawn so that a new rejection can be made.

The allowance of claims 31-34 is withdrawn so that a new rejection can be made.

Claims 31-36 are presented for examination.

Applicants' amendment and response filed November 14, 2008 have been received and entered.

Accordingly, the rejection made under 35 USC 103(a) as being obvious over Meguro et al. (4,687,777) in view of Windholz et al. (PTO-1449) as set forth in the previous Office action dated July 11, 2008 at pages 2-3 as applied to claims 16 and 24 is hereby withdrawn because of applicants' amendment.

Accordingly, the rejection made under 35 USC 103(a) as being obvious over Meguro et al. (4,687,777) as set forth in the previous Office action dated July 11, 2008 at pages 3-4 as applied to claims 9 and 18 is hereby withdrawn because of applicants' amendment.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 31-36 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating acidosis in a mammal in need thereof which comprises administering to said mammal an effective amount of an insulin sensitizer in combination with insulin or an insulin sensitizer alone wherein the insulin

sensitizer is selected from pioglitazone or a salt thereof, wherein said acidosis is caused by metformin; and treating acidosis in a mammal in need thereof which comprises administering to said mammal an effective amount of an insulin sensitizer in combination with insulin or an insulin sensitizer alone wherein the insulin sensitizer is selected from pioglitazone or a salt thereof, wherein said acidosis is diabetic acidosis and the mammal has type II diabetes, does not reasonably provide enablement for improving (preventing) acidosis in a mammal in need thereof which comprises administering to said mammal an effective amount of an insulin sensitizer in combination with insulin or an insulin sensitizer alone wherein the insulin sensitizer is selected from pioglitazone or a salt thereof, wherein said acidosis is caused by metformin; and improving (preventing) acidosis in a mammal in need thereof which comprises administering to said mammal an effective amount of an insulin sensitizer in combination with insulin or an insulin sensitizer alone wherein the insulin sensitizer is selected from pioglitazone or a salt thereof, wherein said acidosis is diabetic acidosis and the mammal has type II diabetes. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

In this regard, the application disclosure and claims have been compared per factors indicated in the decision In re Wands, 8 USPQ2d 1400 (Fed. Cir., 1988) as to undue experimentation.

The factors include:

- 1) the quantity of experimentation necessary

- 2) the amount of direction or guidance provided
- 3) the presence or absence of working examples
- 4) the nature of the invention
- 5) the state of the art
- 6) the relative skill of those in the art
- 7) the predictability of the art and
- 8) the breadth of the claims

The instant specification fails to provide guidance that would allow the skilled artisan background sufficient to practice that instant invention without resorting to undue experimentation in view of further discussion below.

The nature of the invention, state of the prior art, relative skill of those in the art and the predictability of the art

The claimed invention relates to a method for improving (preventing) acidosis in a mammal in need thereof which comprises administering to said mammal an effective amount of an insulin sensitizer in combination with insulin or an insulin sensitizer alone wherein the insulin sensitizer is selected from pioglitazone or a salt thereof, wherein said acidosis is caused by metformin; and improving (preventing) acidosis in a mammal in need thereof which comprises administering to said mammal an effective amount of an insulin sensitizer in combination with insulin or an insulin sensitizer alone wherein the insulin sensitizer is selected from pioglitazone or a salt thereof, wherein said acidosis is diabetic acidosis and the mammal has type II diabetes.

In the specification on page 31, lines 16-22, the section indicates the concept that "improving acidosis" is meant to be a practice of the active agent for "preventing" diseases.

The relative skill of those in the art is generally that of a Ph.D. or M.D.

There are no known preventive therapies for acidosis caused by metformin or diabetic acidosis in a mammal with type II diabetes in the art.

It is clear the art to which the present invention relates is highly unpredictable and unreliable with respect to conclusions drawn from laboratory data extrapolated to clinical efficacy.

The amount of direction or guidance provided and the presence or absence of working examples

There are no examples showing the instant active agent alone or in combination with insulin will, in fact, prevent acidosis caused by metformin or prevent diabetic acidosis in a subject not presently at risk of or predisposed to developing such a disease. No examples showing the instant active agent alone or in combination with insulin is administered to a healthy subject not having acidosis, and the administration of the instant invention will prevent the subject from becoming afflicted with acidosis during its lifetime. Current modes of treatment are known, but there are no known agents, which can be, prevent the causes of acidosis in a healthy subject.

The quantity of experimentation necessary

Applicants have failed to provide guidance as to which cause would be prevented for acidosis and diabetic acidosis in a mammal with type II diabetes. The skilled artisan

would expect the interaction of a particular drug in the prevention of causes of acidosis (any form) to be very specific and highly unpredictable absent a clear understanding of the structural and biochemical basis of the agent. The instant specification sets forth no such understanding nor any criteria for extrapolating beyond the administration of the instant active agent alone or in combination with insulin. Even for the data presented, no direction is provided to prevent specific causes of acidosis. Absent reasonable *a priori* expectations of success, one skilled in the art would have to test extensively many conditions that may lead to acidosis to discover which cause is prevented. Since each prospective embodiment, as well as future embodiments as the art progresses, would have to be empirically tested, undue experimentation would be required to practice the invention as it is claimed in its current scope. The specification provides inadequate guidance to do otherwise.

Claims 31-36 are not allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kevin E. Weddington whose telephone number is (571)272-0587. The examiner can normally be reached on 12:30 pm-9:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on (571)272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Kevin E. Weddington
Primary Examiner
Art Unit 1614

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